Telephone Consent

Only for use when studies are conducted over the phone

*Instructions are in red and should be removed before submitting for IRB review.*

*Suggested text is in black italics*

*If you are obtaining telephone consent, you must submit a telephone script containing all main elements of informed consent. You will also be required to submit a waiver of documentation of consent (click on the link below):*

<https://openredcap.nyumc.org/apps/redcap/surveys/?s=ATA4W8PXTN>

*Basic Elements of Informed Consent:*

*1) A statement that the study involves research 2) Research purpose and procedures 3) Duration of subjects’ expected participation in the research 4) Risks 5) Benefits 6) Alternative to participation (if any) 7) Contact name and contact information 8) Voluntary participation 9) Privacy and Confidentiality*

The following is a sample. It should be modified to fit the specific study.

Hello, my name is\_\_\_\_\_\_\_\_\_\_\_. I am a *student/faculty member/staff member)* from NYU Langone Health conducting research titled \_\_\_\_\_\_\_\_about \_\_\_\_\_\_\_\_\_\_\_\_.

Add if applicable:

Dr. \_\_\_\_\_\_\_\_\_\_ (name of treating physician) told me that you have agreed to be contacted.
-OR-
(*if you have obtained their information from Datacore)*
I am contacting you because information in your medical record indicates that you may be eligible for participation in the study. We have not accessed your medical record but we have obtained your name from NYU Langone MCIT’s Datacore as someone who may be eligible given the study criteria. The purpose of this call is to see if you meet the eligibility criteria and if you would be interested in learning more about the study.

If you feel you have been contacted for this study in error, please let me know. If you would like to remove your name from our contact list for future research studies, please call (1-855-777-7858) or email (research-contact-optout@nyumc.org).

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I am calling to ask you if you are interested in participating in this research study. Your participation is completely voluntary. This means that you do not have to participate in this study unless you want to*.*

*-OR-*

*(if the participant has called to enroll in a study after viewing an advertisement)*

Thank you for calling, we appreciate your interest in this study. Let me tell you more about this study and what will be required of you.

*---*Your decision whether or not to participate in this study will not affect your relationship with your *(medical providers, university, community leaders, etc., as applicable).* If you do not agree to verbally consent to participating in this study, you will continue to receive appropriate medical care.

Would you be willing to hear more information about this study?

*(If yes, continue with below.* *If no, thank them for their time and end the call.*)

I appreciate your time.

Thank you for agreeing to continue. Let me tell you more about this study and what will be required of you.

(*Include here* *a brief general overview of the study).*

The purpose of this research study is to (*look at the relationship between, etc. – make it ‘study specific’*).

*You may find some questions difficult or sensitive in nature and do not wish to answer, just tell me and we will go on to the next question.*

This study will be looking at ------ .

We will ask you to be a part of (*this phone call only and we will ask you to complete a survey, questionnaires list what will be done)*

Your participation will take approximately (state the time of subject participation in hours, days, weeks, months etc. and any follow up calls)

If you agree to participate, you will be asked to (*answer a series of questions* on *make it study specific*).

We estimate that approximately --- (*list number of subjects*) subjects will enroll in this study.

The risks in participating in this study are: (*list risks and if possible qualify the severity by stating rare risks, expected risks frequent risks etc.)*

Although this study may not benefit you personally, we hope that our results will add to the knowledge about\_\_\_\_ *(note: state if there is a direct benefit to participants*)

Would you like me to continue describing the study?

*(If yes, continue with below.* *If no, thank them for their time and end the call.*)

You will *(not)* be compensated *(state the amount and how it will be received).* You will not have to pay for any research related expenses.

We are committed to protecting your privacy and maintaining confidentiality. We will not identify you by name or any other information that would make it possible for anyone to identify you in any presentation or written reports about this study.

(Choose below as applicable, add)

When this call is completed all the (*surveys, questionnaires, etc*.), I will group all the answers together with the other participants in one report. There will be no way to identify individual participants.

All information that I receive from you by phone will be strictly confidential and will be kept under lock and key.

If it is okay with you, I might want to use direct quotes from you, but these would only be cited as ‘from a person’.

To do this research, we need to temporarily collect some health information that identifies you. We may temporarily collect (*the results of tests, questionnaires, interviews, and collect information from your medical record*). We will only collect information that is needed for the research.

Once I gather the required information, I will delete any identifying information related to you, such as your name or medical record number. For you to be in this research, we will need your permission to collect this information. Only research personnel authorized for this study will have access to your health information.

IF a waiver of authorization is not applicable add the next 3 paragraphs:

*If you agree to participate in this study, I will mail you a HIPAA Authorization form (‘permission form’). This form outlines specifically how we will use your personal health information for this study.*

Please read the HIPAA Authorization form carefully, and if you feel that the conditions outlined are agreeable to you, please sign and mail the form back in the envelope provided (*or to the address specified*).

If you do not sign and mail back the HIPAA authorization form, we will not be able to include you in the study, and we will remove any information we have collected about you.

If you change your mind later and do not want us to use your information, and responses in this study, please send a letter to the Principal Investigator (*name and mailing address*). At that time we will remove any information we have collected about you in regards to this study.

You can call (*Principal Investigator/Researcher*) at (*telephone*) with any questions about this study. If you have any questions regarding your rights as a research subject, please contact the Institutional Review Board (IRB) at 212-263-4110.

Do you have any questions at this time?

Would you like to participate in this research?

*If ‘no’, thank them for their time and end the call.*

*If ‘yes’, begin asking questions/conduct an interview.*

**e-Consent Instructions**
If your study has been approved to use electronic informed consent (e-Consent) processes to consent subjects remotely, send a link to the consent materials to the participant through SendSafe or REDCap.

If you have NOT been approved to use e-Consent:

We can schedule an appointment for you to come on-site to discuss study materials. What would be a convenient time for you to come to (location)?

If they are eligible proceed with:

We are able to send the informed consent materials electronically to you through (SendSafe/REDCap). Would you prefer that we send the form to your NYU Langone Health account, or another email address?

*If other email address:*

We will send the consent form to you using SendSafe.